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510(k) Summary of Safety and Effectiveness for the DUSA PanaLight-BLU™ Illuminator, Model 4175

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SDMA 1990 and 21 CFR 807.92.

Applicant & Submitter:	DUSA Pharmaceuticals, Inc.
Address:	25 Upton Drive Wilmington, MA 01887
Phone:	978-657-7500
FAX:	978-657-9193
Contact Person:	Scott Lundahl
Preparation Date:	November 15, 2004
Device Submitted:	PanaLight-BLU™ Illuminator, Model 4175
Proprietary Name:	PanaLight-BLU™
Common Name:	Blue Light Illuminator
Classification Name:	Laser surgical instrument for use in General and Plastic Surgery and in Dermatology. Product Code GEX
Predicate Devices:	BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170 and ClearLight™ Phototherapy Device, Model CL-420
Device Description:	The PanaLight-BLU™ is a compact light source that delivers a uniform distribution of narrowband blue light to the body with a spectral output at a peak wavelength of 417 $\pm$ 5 nm. The principal parts of the system include the light unit head and floor stand with timer.
Intended Use:	The PanaLight-BLU™ Illuminator, Model 4175 is intended to provide phototherapeutic light to the body. The PanaLight-BLU™ is generally indicated to treat dermatological indications. The PanaLight-BLU™ is specifically indicated to treat moderate inflammatory acne vulgaris.
Performance Data:	No performance data is required for this Class II device nor has it been requested by the Food and Drug Administration (Office of Device Evaluation). The PanaLight-BLU™ has the same spectral output, mode of operation, treatment area, and general operating principals as well as the same intended use,

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	the same general and specific indications for use as the predicate devices. Based on an analysis of the overall performance characteristics, no significant differences exist and therefore the PanaLight-BLU™ raises no new questions of safety or efficacy.
Substantial Equivalence:	The PanaLight-BLU™ Illuminator is substantially equivalent to the previously cleared BLU-U® Blue Light Photodynamic Therapy Illuminator, Model 4170, and to the previously cleared ClearLight™ Phototherapy Device, Model CL-420.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 10 2004

Mr. Scott Lundahl
Vice President Regulatory Affairs
DUSA Pharmaceuticals, Inc.
25 Upton Drive
Wilmington, Massachusetts 01887

Re: K043164
Trade/Device Name: PanaLight-BLU™ Illuminator
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: November 15, 2004
Received: November 16, 2004

Dear Mr. Lundahl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K043164 (if known)

Device Name: PanaLight-BLU™ Illuminator

Indications for Use: The PanaLight-BLU™ Model 4175 is intended to provide phototherapeutic light to the body. The PanaLight-BLU™ is generally indicated to treat dermatological indications. The PanaLight-BLU™ is specifically indicated to treat moderate inflammatory acne vulgaris.

Prescription Use X AND/OR Over-The-Counter Use ____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE OF ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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